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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,784	03/19/2004	Rodney Scott Armentrout	71418/US02	7760
71466	7590	10/30/2007	EXAMINER	
LOUIS N. MORENO			MULLIS, JEFFREY C	
P.O. BOX 511 , B-75			ART UNIT	PAPER NUMBER
KINGSPORT, TN 37662			1796	
			MAIL DATE	DELIVERY MODE
			10/30/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/804,784

Applicant(s)

ARMENTROUT ET AL.

Examiner

Jeffrey C. Mullis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2007.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10, 15 and 17-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 15 and 17-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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Claims 1-10, 15, and 17-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 in part "B" recites an end capping reagent "selected from the group consisting of a cyclic anhydride; and a multifunctional acid" and thus claim 1 is worded such that it would appear that a combination of multifunctional acid and anhydride is required (in that the ";" would appear to end the Markush group while "and" implies a combination) when in fact applicants remarks during prosecution give no hint that a combination of acid and anhydride is intended.

Claims 1-10, 15 and 17-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as filed does not disclose the use of a combination of acid and anhydride reagents but rather discloses only use of these as alternatives and the limitation reagent "selected from the group consisting of a cyclic anhydride; and a multifunctional acid" is therefore new matter.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-10, 15 and 18-22 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bae et al (US 2005/0186263).

Bae discloses a block copolymer containing a polyhistidine block or polylactic acid blocks as in applicants hard block and also containing a PEG block and in which folic acid (a diacid) is bound as an end group in applicants proportions based on the disclosed molecular weight of the blocks. See examples at paragraphs 124, 125 and 149 in this re. With re to blends with thermoplastics see paragraph 56 for addition of CMC. Given that the reaction of dicarboxylic acids with DCC is known to produce cyclic anhydrides (see Kung et al., CAPLUS AN 1987:81167) it is reasonable that at least a small amount of anhydride (resulting from reaction of folic acid and DCC) is produced in Baes' Example 11. However, even assuming that the examiner is incorrect and that the "preactivated" folic acid of Bae contains no anhydride whatsoever, applicants embodiments utilizing a folic acid anhydride reads on Baes' products of at least Example 11 of Bae in that both Baes' product and applicants embodiment where an

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anhydride of folic acid is reacted with a PEG containing block copolymer in that both products would contain a folic acid residue bound via the carboxyl group to the PEG moiety.

Product-by-process claims are not rejected using the approach set out in Graham v. Deere. It is applicant's burden to show that there is a non-obvious difference between the product of a product-by-process claim and a prior art product which reasonably appears to be the same or only slightly different whether or not the prior art product is produced in the same manner as the claimed product. Note In re Marosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972) and In re Thorpe, 227 USPQ 964 (CAFC 1985) in this regard.

Applicant's arguments filed 8-13-07 have been fully considered but they are not persuasive. Given that the reaction of dicarboxylic acids with DCC is known to produce cyclic anhydrides (see Kung et al., CAPLUS AN 1987:81167) it is reasonable that at least a small amount of anhydride (resulting from reaction of folic acid and DCC) is produced in Baes' Example 11. However, even assuming that the examiner is incorrect and that the "preactivated" folic acid of Bae contains no anhydride whatsoever, applicants embodiments utilizing a folic acid anhydride reads on Baes' products of at least Example 11 of Bae in that both Baes' product and applicants embodiment where an anhydride of folic acid is reacted with a PEG containing block copolymer in that both

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products would contain a folic acid residue bound via the carboxyl group to the PEG moiety.

Any inquiry concerning this communication should be directed to Jeffrey C. Mullis at telephone number 571 272 1075.

Jeffrey C. Mullis  
J Mullis  
Art Unit 1796

JCM

10-24-07

A handwritten signature in black ink, appearing to be 'JCM', located below the typed name of Jeffrey C. Mullis.